County having social and economic affiliation with the Tribe.

(3) Although the Tribe's reservation is in Clallam County, the Tribe has trust land in Jefferson County that is included in an approved land consolidation plan and is pending proclamation to add it to the Tribe's reservation. This tribal trust land is contiguous to the existing reservation and extends into Jefferson County.

(4) It is estimated that the current eligible contract health service population will be increased by 39 individuals, changing the active patient population from 192 to 231, assuming 100 percent utilization for Jefferson County eligibles. Based upon data from the fiscal year 1994 application of the health services priority system and the modified resource requirements methodology, the total clinical work units (CWU's) generated by the user population of 192 was 998.4, or 5.2 per individual. Assuming the same utilization, the 39 new users will generate an additional 202.8 CWU's. The calculated cost per CWU in the inpatient and ambulatory contract health care category was $139.22 for the Tribe. Therefore, potential added costs for contract health services resulting from new users is approximated at $139.22 X 202.8 CWU's = $28,233.82. Total resources available to the program in fiscal year 1994 were $139,000. The addition of new usage would not be expected to result in an increase in funding for the Tribe. The impact on existing contract health services will not be substantial. The current funding level will allow sufficient flexibility to assure that there will be no significant reduction in the level of contract health services to current CHSDA residents, so the designation of the two-county CHSDA is within available resources.

Accordingly, after considering the Tribe's request in light of the criteria specified in the regulations, I am proposing to redesignate the CHSDA of the Tribe to consist of Clallam and Jefferson Counties of the State of Washington.

This notice does not contain reporting or recordkeeping requirements subject to prior approval by the Office of Management and Budget under the Paperwork Reduction Act of 1930.

Dated: May 23, 1995.

Michel E. Lincoln,

Acting Director.

[FR Doc. 95–19095 Filed 8–2–95; 8:45 am]

BILLING CODE 4160–16–M

Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility

AGENCY: Public Health Service, HHS.

ACTION: Notice.

SUMMARY: Section 602 of Public Law 102–585, the ''Veterans Health Care Act of 1992,'' enacted section 340B of the Public Health Service Act (PHS Act), ''Limitation on Prices of Drugs Purchased by Covered Entities.'' Section 340B provides that a manufacturer who sells covered outpatient drugs to eligible entities must sign a pharmaceutical pricing agreement with the Secretary of Health and Human Services in which the manufacturer agrees to charge a price for covered outpatient drugs that will not exceed that amount determined under a statutory formula.

The purpose of this notice is to inform interested parties of decisions regarding certain issues of program implementation. The notice will discuss the determination of covered entity status (i.e., PHS entity and disproportionate share hospital eligibility) and the administrative program requirements for ''covered entity'' status. Further, PHS is proposing a definition of eligible covered entity ''patient'' in section III for public comment.

DATES: The public is invited to submit comments on the proposed definition of ''patient'' in section III by September 5, 1995. After consideration of the comments submitted, the Secretary will issue the final guidelines.

FOR FURTHER INFORMATION CONTACT: Marsha Alvarez, R. Ph., Attn: Drug Pricing Program, Bureau of Primary Health Care, 4350 East West Highway, 10th Floor, Bethesda, MD 20814, Phone (301) 594–4353.

SUPPLEMENTARY INFORMATION: The Office of Drug Pricing has developed the following guidelines to facilitate program implementation and is proposing a definition of ''patient'' in section III for public comment.

I. Covered Entity Status

PHS Entities

Section 340B(a)(4) of the PHS Act lists the various categories of PHS programs eligible to receive section 340B outpatient drug discount pricing. For each category, there is a Federal program office which oversees the grant program. The respective Federal program offices determine which individual facilities receive the grant funds specified by section 340B or are eligible under other criteria and compile a list of such entities. The Federal program office then submits this list to the Office of Drug Pricing (ODP) for inclusion on the master list of eligible facilities (''covered entities'').

Each program office is responsible for maintaining a current data file of eligible entities and submitting all updated information to the ODP. This information may either be submitted on a quarterly or yearly basis, depending upon the number of entity status changes in a given period. Each program office determines how often updates are necessary to maintain current entity information on the ODP master list of covered entities and notifies the ODP of their respective update time periods. The update file data is submitted to ODP in either a dbf or ASCI file, the formats of which are available from the ODP. Program offices submit their updates to the ODP on the following dates: (a) December 1 for the January 1 update, (b) March 1 for the April 1 update, (c) June 1 for the July 1 update, and (d) September 1 for the October 1 update.

The ODP will update the master covered entity file on a quarterly basis. The name of an entity will not be added or deleted at any other time. For example, if an entity becomes an eligible PHS grantee, its name will not appear on the ODP master list until the program office submits the name in its update package and the ODP subsequently updates the ODP master list during the next quarterly cycle. ODP will not directly add to or delete an entity name from the ODP master list. An entity name to be added or deleted must be submitted by the program office during a scheduled update period.

The following is a list of the Federal program offices which oversee the 340B eligible programs and contact persons (except as otherwise indicated, references are to sections of the Public Health Service Act):

1. Federally-qualified health center, as defined in section 1905(1)(2)(B) of the Social Security Act (42 U.S.C. § 1396d(1)(2)(B)), means an entity that:

(a) receives a grant under section 329 (migrant health center), section 330 (community health center), section 340 (health services for the homeless), and section 340A (health services for residents of public housing); or

(b) (i) receives funding from such a grant under a contract with the recipient of the grant, and (ii) meets the requirements to receive a grant under section 329, 330, 340 and 340A; or

(c) based on the recommendation of the Health Resources and Services Administration (HRSA) within the Public Health Service, is determined by the Secretary to meet requirements for

receiving such a grant (i.e., ''look-alikes''); or

(d) was treated by the Secretary, for purposes of part B of Title XVIII of the Social Security Act, as a comprehensive Federally funded health center as of January 1, 1990; or

(e) an outpatient health program or facility operated by a tribe or tribal organization under the Indian Self-Determination Act (Public Law 93–638) or by an urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act for the provision of primary health services. (Norma Campbell, Division of Community and Migrant Health, 301–594–0287), (Marie Garramone, Division of Community and Migrant Health {for look-alikes}, 301–594–4335), (Charles Woodson, Division of Programs for Special Populations, homeless and public housing health centers, 301–594–4430: Laura Visser, {for 340S school based programs}, 301–594–4470), (Elmer Brewster, DCSP, Special Initiatives Branch {for Urban Indian}, 301–443–4680), and (Merry Elrod, Office of Tribal Activities {for P.L. 93–638}, 301–443–1044).

2. Family planning projects receiving grants or contracts under section 1001, 42 U.S.C. 300. (Sophia Lawson, Office of Population Affairs, 301–594–4000).

3. An entity receiving a grant for outpatient early intervention services for HIV infection under subpart II of part C of title XXVI, 42 U.S.C. 300ff–51 *et seq.* (Laverne Green, Office of Programs for Special Populations, HIV, 301–594–4451).

4. A State-operated AIDS drug purchasing assistance program receiving financial assistance under section 2616 of the Act, 42 U.S.C. 300ff–26. (Richard Schulman, Division of HIV Services, 301–443–9091).

5. A black lung clinic receiving funds under section 427(a) of the Black Lung Benefits Act, 30 U.S.C. 937(a). (Norma Campbell, Division of Community and Migrant Health, 301–594–0287).

6. A comprehensive hemophilia diagnostic treatment center receiving a grant under section 501(a)(2) of the Social Security Act, 42 U.S.C. 701(a)(2). (Patrick McGuckin, National Hemophilia Program, 301–443–9051).

7. A Native Hawaiian Health Center receiving funds under the Native Hawaiian Health Care Act of 1988, 42 U.S.C. 11701 *et seq.* (Julia Tillman, Division of Programs for Special Populations, 301–594–4460).

8. Certain covered facilities must be certified by the Secretary before they become eligible for the discount drug prices, pursuant to section 340B(a)(7) of the PHS Act. The facilities requiring certification are those that

(a) receive grant funds related to the treatment of sexually transmitted diseases through a state or local government under section 318 of the PHS Act, 42 U.S.C. 247c, or related to the treatment of tuberculosis through a state or local government under section 317 E (a) of the PHS Act, 42 U.S.C. 247b–6, (Carmine Bozzi, Centers for Disease Control and Prevention, National Center for Prevention Services, 404–639–8008), or

(b) receive assistance under title XXVI of the PHS Act, 42 U.S.C. 300ff *et seq.*, other than a State or unit of local government or a grantee for HIV outpatient early intervention services (subpart II of part C of title XXVI of the PHS Act). (Richard Schulman, Division of HIV Services, 301–443–9091).

The criteria for eligibility include State certification that the facility does receive Federal grant funds and is a facility described in (a), or (b) above.

Electronic Data Retrieval System (EDRS) which can be accessed by dialing (301) 594–4992.

Disproportionate Share Hospitals

Certain hospitals are eligible for section 340B discount outpatient drug pricing if they meet the eligibility criteria. First, section 340B(a)(4)(L)(ii) provides that a hospital must be a ''disproportionate share'' hospital (DSH) as defined in section 1886(d)(1)(B) of the Social Security Act, which (for the most recent cost reporting period that ended before the calendar quarter involved) had a disproportionate share adjustment greater than 11.75 percent. This percentage is determined by the Health Care Financing Administration (HCFA), and a list of DSHs which meet this criteria is provided to the Office of Drug Pricing.

Second, section 340B(a)(4)(L)(i) provides that DSHs eligible for PHS pricing must meet one of the following requirements: (1) is owned or operated by a unit of State or local government, (2) is a public or private non-profit corporation which is formally granted governmental powers by a unit of State or local government, or (3) is a private nonprofit hospital which has a contract with a State or local government to provide health care services to low income individuals who are not entitled to benefits under title XVIII or XIX of the Social Security Act. All DSHs wishing to have access to section 340B discount outpatient drug pricing must provide the ODP a certification of their compliance with one of the three alternative requirements.

Third, a DSH is prohibited from participating in a group purchasing organization or any group purchasing association, pursuant to section 340B(a)(4)(L)(iii). DSHs wishing to access the discount pricing must provide the Office of Drug Pricing with a certification of their compliance with this prohibition.

DSHs must submit all necessary certifications to the Public Health Service DSH contact person—Elizabeth Hickey, Office of Drug Pricing, Bureau of Primary Health Care, West Tower, 10th Floor, 4350 East West Highway, Bethesda, Maryland, 20814, telephone (301) 594–4353.

II. Entity Participation Requirements

Section 340B(a)(4) of the PHS Act defines a ''covered entity'' as belonging to one or more of the eligible categories of PHS grantees or disproportionate share hospitals listed in subparagraph (4) and meeting the requirements of subparagraph (5). Subparagraph (5)(A) requires HHS to develop a mechanism to prevent a double PHS discount/Medicaid rebate potential; therefore, as part of this mechanism, each eligible entity must provide the ODP with certification of its pharmaceutical Medicaid billing status. Any entity which does not comply with this requirement will not be deemed a ''covered entity'' and will not be eligible for section 340B drug discounts. Those entities currently listed on the ODP master list which have not certified their Medicaid billing status will be removed from the ODP master list unless they certify their current billing status by the next quarterly update. Entities listed on subsequent program updates will be given one quarter from the date of the program update or until the next ODP update to certify their Medicaid billing status to ODP. Once the entity has certified its Medicaid billing status, its name will be included on the master list as a covered entity on the next ODP update.

A certification of the following information must be provided to the ODP before an entity will be deemed a ''covered entity:'' First, a covered entity, billing on a cost basis for covered outpatient drugs, must provide the ODP with a pharmaceutical Medicaid number (the number which the entity uses to bill Medicaid for such drugs). Second, a covered entity using an all-inclusive rate (either per encounter or visit) must provide the ODP with certification of this billing status and whether the all-inclusive rate includes covered outpatient drugs. Third, if a covered entity does not bill Medicaid for covered outpatient drugs, the entity

must notify the ODP of this decision. Fourth, a facility which houses many different clinics, only one or several of which are eligible, must obtain a separate Medicaid provider number for the eligible clinics. For those States which cannot generate additional Medicaid provider numbers for entities, the covered entity must discuss and implement an alternative arrangement with the States to prevent the duplicate PHS discount/Medicaid rebate potential. *See* 59 FR 25112 (May 13, 1994). Please note that only covered entities wishing to access the PHS discount pricing should certify their pharmaceutical Medicaid billing status to ODP.

III. Definition of Eligible Entity ''Patient''

Section 340B(a)(5)(B) of the PHS Act states that the covered entity must provide drugs, discounted under the statute, only to its patients and not resell or otherwise transfer such drugs to individuals who are not patients of the entity. To address the potential for drug resale or transfer, PHS published final entity guidelines concerning drug diversion. See 59 Fed. Reg. 25112, May 13, 1994. In part, covered entities are required to ''develop and institute adequate safeguards to prevent the transfer of discounted outpatient drugs to individuals who are not eligible for the discount.'' To accomplish this end, entities are encouraged to utilize a separate purchasing account and separate dispensing records. To further address the potential for drug diversion, PHS is now proposing a definition of a covered entity ''patient.''

An individual is a ''patient'' of a covered entity (with the exception of State-operated AIDS drug purchasing assistance programs) only if:

1. the covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care; and

2. the individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g. referral for consultation) such that responsibility for the care provided remains with the covered entity; and

3. the individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding or Federally-qualified health center look-alike status has been provided to the entity. Disproportionate share hospitals are exempt from this requirement.

An individual will not be considered a ''patient'' of the entity for purposes of 340B if the only health care service received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting.

An individual registered in a State-operated AIDS drug purchasing assistance program receiving financial assistance under title XXVI of the PHS Act will be considered a ''patient'' of the covered entity for purposes of this definition if so registered as eligible by the State program.

Dated: June 5, 1995.

Ciro V. Sumaya,

Administrator, Health Resources and Services Administration.

[FR Doc. 95–19061 Filed 8–2–95; 8:45 am]

BILLING CODE 4160–15–P

Substance Abuse and Mental Health Services Administration

Current List of Laboratories Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies and Laboratories That Have Withdrawn From the Program

AGENCY: Substance Abuse and Mental Health Services Administration, HHS (Formerly: National Institute on Drug Abuse, ADAMHA, HHS).

ACTION: Notice.

SUMMARY: The Department of Health and Human Services notifies Federal agencies of the laboratories currently certified to meet standards of Subpart C of Mandatory Guidelines for Federal Workplace Drug Testing Programs (59 FR 29916, 29925). A similar notice listing all currently certified laboratories will be published during the first week of each month, and updated to include laboratories which subsequently apply for and complete the certification process. If any listed laboratory's certification is totally suspended or revoked, the laboratory will be omitted from updated lists until such time as it is restored to full certification under the Guidelines.

If any laboratory has withdrawn from the National Laboratory Certification Program during the past month, it will be identified as such at the end of the current list of certified laboratories, and will be omitted from the monthly listing thereafter.

FOR FURTHER INFORMATION CONTACT: Mrs. Giselle Hersh, Division of Workplace Programs, Room 13A–54, 5600 Fishers Lane, Rockville, Maryland 20857; Tel.: (301) 443–6014.

SUPPLEMENTARY INFORMATION:

Mandatory Guidelines for Federal Workplace Drug Testing were developed in accordance with Executive Order 12564 and section 503 of Pub. L. 100–71. Subpart C of the Guidelines, ''Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies,'' sets strict standards which laboratories must meet in order to conduct urine drug testing for Federal agencies. To become certified an applicant laboratory must undergo three rounds of performance testing plus an on-site inspection. To maintain that certification a laboratory must participate in a quarterly performance testing program plus periodic, on-site inspections.

Laboratories which claim to be in the applicant stage of certification are *not* to be considered as meeting the minimum requirements expressed in the HHS Guidelines. A laboratory must have its letter of certification from SAMHSA, HHS (formerly: HHS/NIDA) which attests that it has met minimum standards.

In accordance with Subpart C of the Guidelines, the following laboratories meet the minimum standards set forth in the Guidelines:

Aegis Analytical Laboratories, Inc., 624 Grassmere Park Rd., Suite 21, Nashville, TN 37211, 615–331–5300

Alabama Reference Laboratories, Inc., 543 South Hull St., Montgomery, AL 36103, 800–541–4931/205–263–5745

American Medical Laboratories, Inc., 14225 Newbrook Dr., Chantilly, VA 22021, 703–802–6900

Associated Pathologists Laboratories, Inc., 4230 South Burnham Ave., Suite 250, Las Vegas, NV 89119–5412, 702–733–7866

Associated Regional and University Pathologists, Inc. (ARUP), 500 Chipeta Way, Salt Lake City, UT 84108, 801–583–2787

Baptist Medical Center—Toxicology Laboratory, 9601 I–630, Exit 7, Little Rock, AR 72205–7299, 501–227–2783 (formerly: Forensic Toxicology Laboratory Baptist Medical Center)

Bayshore Clinical Laboratory, 4555 W. Schroeder Dr., Brown Deer, WI 53223, 414–355–4444/800–877–7016

Cedars Medical Center, Department of Pathology, 1400 Northwest 12th Ave., Miami, FL 33136, 305–325–5810

Centinela Hospital Airport Toxicology Laboratory, 9601 S. Sepulveda Blvd., Los Angeles, CA 90045, 310–215–6020

Clinical Reference Lab., 11850 West 85th St., Lenexa, KS 66214, 800–445–6917

CompuChem Laboratories, Inc., 3308 Chapel Hill/Nelson Hwy., Research Triangle Park, NC 27709, 919–549–8263/800–833–3984. (Formerly: CompuChem Laboratories, Inc., A Subsidiary of Roche Biomedical Laboratory, Roche CompuChem Laboratories, Inc., A Member of the Roche Group)